4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2013-F-1540]

DSM Nutritional Products; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that DSM Nutritional Products has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 25-hydroxyvitamin D₃ in feed for laying and breeding hens.

DATES: Submit either electronic or written comments on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to: http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2277)

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has been filed by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The

petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 Food

Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for

the safe use of 25-hydroxyvitamin D₃ in feed for laying and breeding hens.

The petitioner has requested a categorical exclusion from preparing an environmental

assessment or environmental impact statement under 21 CFR 25.32(r). Interested persons may

submit either electronic or a single copy of written comments regarding this request for

categorical exclusion to the Division of Dockets Management (see DATES and ADDRESSES).

Identify comments with the docket number found in brackets in the heading of this document.

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4

p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: December 17, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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